Life Spine®

K061364

510(k) Summary of Safety and Effectiveness

510(k) Summary - PILOT™ Posterior Lumbar Plating System

SEP - 5 2006

Submitted By:

Life Spine
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510(k) Contact:

Erin Malloy
Life Spine
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Hoffman Estates, IL 60195
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Date Prepared: August 2, 2006

Trade Name: PILOT™ Posterior Lumbar Plating System

Common Name: Posterior Pedicle screw system

Classification: 21 CFR 888.3070
Pedicle Screw Spinal System
Class II

Device Product Code: *MNI: Orthosis, Spinal, Pedical Fixation*
MNH: Orthosis, spondylolisthesis spinal fixation

Predicate Device: Predicate device information is included in this premarket notification

Device Description:

When implanted in the thoracic, lumbar, and/or sacral spine, the PILOT™ Plating System provides additional support during spinal fusion. The PILOT™ Plating System consists of bone screws, plates, washers, nuts, and collets in various shapes and sizes. The PILOT™ Plating System is manufactured from medical grade titanium and will be sold non-sterile.

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and hold an alignment in place until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The PILOT™ Plating System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization

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and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

The PILOT™ Posterior Lumbar Plating System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation) (4) spinal stenosis, (5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis) (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

Material:

The PILOT™ Plating System is manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6AL-4V-ELI).

Performance Data:

Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

Substantial Equivalence:

The Life Spine PILOT™ Plating System was shown to be substantially equivalent to a previously cleared device in indications for use, design, function, and materials used.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Life Spine
% Ms. Erin Malloy
Project Engineer
2400 Hassell Road, Suite 370
Hoffman Estates, Illinois 60195

SEP - 5 2006

Re: K061364
Trade/Device Name: PILOT™ Posterior Lumbar Plating System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: August 2, 2006
Received: August 4, 2006

Dear Ms. Malloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruch MD
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

Indications for Use

510(k) number (if known): K061364

Device Name: PILOT™ Posterior Lumbar Plating System

Internal fixation implants are load-sharing devices intended to stabilize and hold an alignment in place until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The PILOT™ Posterior Lumbar Plating System, when properly used, is intended for posterior pedicle screw fixation of the non-cervical posterior spine in skeletally mature patients. It provides stabilization and immobilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities.

The PILOT™ Posterior Lumbar Plating System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spondylolisthesis, (3) trauma (i.e., fracture or dislocation) (4) spinal stenosis, (5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis) (6) tumor, (7) pseudoarthrosis, (8) failed previous fusion.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061364

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